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EXAMINER

ALLEN, MARIANNE P

ART UNIT

PAPER NUMBER

1631

DATE MAILED: 07/21/2003

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Please find below and/or attached an Office communication concerning this application or proceeding.

# Office Action Summary

Application No.

09/629,557

Applicant(s)

MILLER ET AL.

Examiner

Marianne P. Allen

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

## Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

## Status

- 1) ☒ Responsive to communication(s) filed on 5/9/03 (request for RCE).
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

## Disposition of Claims

- 4) ☒ Claim(s) 1-3,5-11,13,14,17-26,55-58 and 65-93 is/are pending in the application.
- 4a) Of the above claim(s) \_\_\_\_\_ is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 1-3,5-10,14,18-26,55-58,66-69,75-80 and 82-93 is/are rejected.
- 7) ☒ Claim(s) 11, 13, 17, 65, 70-74, 81 is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

## Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
- Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- 11) ☐ The proposed drawing correction filed on \_\_\_\_\_ is: a) ☐ approved b) ☐ disapproved by the Examiner.
- If approved, corrected drawings are required in reply to this Office action.
- 12) ☐ The oath or declaration is objected to by the Examiner.

## Priority under 35 U.S.C. §§ 119 and 120

- 13) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some \* c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- \* See the attached detailed Office action for a list of the certified copies not received.
- 14) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).
- a) ☐ The translation of the foreign language provisional application has been received.
- 15) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

## Attachment(s)

- 1) ☐ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☐ Information Disclosure Statement(s) (PTO-1449) Paper No(s) \_\_\_\_\_.
- 4) ☐ Interview Summary (PTO-413) Paper No(s). \_\_\_\_\_.
- 5) ☐ Notice of Informal Patent Application (PTO-152)
- 6) ☐ Other: \_\_\_\_\_.

### **DETAILED ACTION**

Claims 4, 12, and 15-16 have been cancelled. Claims 91-93 have been newly introduced. Claims 1-3, 5-11, 13-14, 17-26, 55-58, and 65-93 are under consideration by the examiner.

The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office action.

Applicant's arguments filed 5/9/03 have been fully considered but they are not persuasive.

#### ***Claim Rejections - 35 USC § 101***

Claims 25-26 and 90 are rejected under 35 U.S.C. 101 because the claimed invention is directed to non-statutory subject matter.

Claims 25 is directed to a computer readable medium having stored thereon instructions for performing the actions of claim 1. Claim 26 is directed to a computer readable medium having stored thereon instructions for performing the actions of claim 18. Claim 90 is directed to a computer readable medium having stored thereon instructions for performing the actions of claim 82. These claims are considered to be directed to data such as a text file (e.g. user's manual) stored on a disk. This is non-statutory subject matter. See MPEP 2106 (IV)(B)(1)(b). Note that these claims do not reflect that the instructions are computer executable instructions nor computer code for performing the actions of claim 1.

***Claim Rejections - 35 USC § 112***

Claim 91 is rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention. This is a new matter rejection.

Claim 91 is a newly introduced claim. Basis is stated to be on page 3. However, testing using a validation set of data and/or leave-one-out cross validation is not synonymous with “validating the spectral data-activity relationship” as recited in the claims. There is no support for the claim as presently written.

Claims 10, 18-24, 26, 56-58, 68, and 82-93 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claims 10 recites “to produce the spectral pattern for the test compound.” There is no antecedent basis in claim 1 as amended for producing a spectral pattern. As such, this claim is confusing.

Claim 18 is confusing in requiring receiving spectral data for a test compound but not clearly setting forth a step where it is used. Note that the final step predicts the biological activity of the test compound using the spectral data-activity relationship but does not indicate that the test compound spectral data is used. Claim 82 is likewise confusing. See by comparison claim 1 which recites “predicting the biological activity of

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the test compound from its segmented spectral data using the spectral data-activity relationship.”

Claim 21 is confusing in reciting “two or more such spectral data.” It is unclear of this limits the composites to those types of spectral data recited previously in the claim or encompasses additional types. See by comparison claim 84.

Claims 78 is confusing and does not clearly further limit claim 75. Claim 78 does not appear to require that the composite of two or more types of spectral data be those recited in claim 75. See by comparison claim 84.

Claim 85 is indefinite in reciting “similar magnitude.” It is not known what level of similarity would meet this limitation. For example, is an NMR structure descriptor of magnitude 10 similar or dissimilar to an MS structure descriptor of magnitude 100? Is an NMR structure descriptor of magnitude 1 similar or dissimilar to an MS structure descriptor of magnitude 5?

### ***Claim Rejections - 35 USC § 102***

Claims 1-3, 5-10, 14, 18-21, 25-26, 55-58, 66-69, 75-80, and 90 are rejected under 35 U.S.C. 102(a) as being anticipated by Bursi et al.

Bursi et al. discloses predicting biological activity for test compounds from their IR, mass, <sup>1</sup>H NMR, and <sup>13</sup>C NMR spectra as descriptors in 3D modeling. A training set of 38 progestagen compounds of known binding activity was used. Some were experimental and some were simulated (calculated). (See page 864, left column, under Results.) Different combinations of spectra were analyzed for their predictive ability. The spectra properties (peaks and intensities) are binned. (See page 862 under

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Computational Details.) Data conversion was performed on the spectral data to present the data in an appropriate format for analysis. (See page 862.) This is deemed to meet the limitation of scaling. In addition, the spectra were normalized to obtain the same total intensity for each spectrum. Each of the bins is considered to be equally weighted meeting the limitation of weighting. With respect to claims 25-26 and 90, these are considered to be limited to a computer readable medium having any data stored on them and are thus anticipated by Bursi et al. (See rejection under 35 USC 101, above.)

### ***Conclusion***


Claims 11, 13, 17, 65, 70-74, and 81 are objected to as being dependent upon a rejected base claim, but would be allowable if rewritten in independent form including all of the limitations of the base claim and any intervening claims.

No claim is allowed.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Marianne P. Allen whose telephone number is 703-308-0666. The examiner can normally be reached on Monday-Friday, 7:00 am - 1:00 pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Michael Woodward can be reached on 703-308-4028. The fax phone numbers for the organization where this application or proceeding is assigned are 703-305-3014 for regular communications and 703-305-3014 for After Final communications.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is 703-308-0196.

  
Marianne P. Allen  
Primary Examiner  
Art Unit 1631

npa  
July 14, 2003